

A. Objection to Drawings Under 37 CFR 1.84(g, i, p)

The drawings are objected to because they contain informalities relating to improper margins, improper shading and legibility. Applicant will file corrected formal drawings upon receipt of Notice of Allowance and Issue Fee Due in the application.

B. Rejection of Claims 1-74 and 105-107 Under 35 U.S.C. § 112

Claims 1 through 74 and 105 through 107 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 stands rejected because the term “sample application” was deemed to be unclear. Claim 2 was also rejected because the phrase “said porous region” is inconsistent with the phrase “first porous silicon region.” Claim 2 has been canceled without prejudice or disclaimer.

Claims 3, 6, 30, 45, 51, 57, 64 and 65 each stand rejected for alleged indefiniteness of the term “defines”. Each of these claims have been amended to delete the term “defines”.

Claim 4 stands rejected for alleged indeterminate scope of the term “extends substantially linearly.” Claim 4 has been amended to recite that the “first porous region linearly traverses” the semiconductor substrate.

Claims 7 and 9 stand rejected for alleged lack of clarity of meaning of the phrase “positioned along and contiguous with.” Claims 7 and 9 have been amended to change the terminology “reactant region” to “reaction region” to more accurately reflect the information contained in the specification and to recite that the reaction region is “intermediately situated along a length of” the first porous region.

Claims 10, 12, 20, 25, 29, 30, 34, 50, 52, 56, 58, 66 and 106 stand rejected because of inconsistent use of the terms “disposed” and “positioned” within the specification. Claims 10, 12, 20, 25, 29, 30, 34, 50, 52, 56, 58, 66 and 106 have each been amended to include the term “situated,” which is also found recited in claims 7 and 9. It is respectfully submitted that the term disposed is more appropriate in claims 25, 34, 66 and 106, as each of those claims recite a

stationary phase, a solid phase, or a capture substrate, which is not situated, but rather disposed on the matrix or on the hemi-spherical grain silicon.

Claims 18, 19, 21 and 39-43 each stand rejected for alleged indefiniteness of the term “associated.” Each of these claims have been amended to include the terminology “in communication”.

Claim 46¹ has been amended to include the term “another” and to thereby distinguish the two elements.

Additionally, independent claim 1 was listed for rejection under Section 112, but the examiner failed to specify what was indefinite in the claim.

B. 35 U.S.C. § 103(a)

Claims 1-4, 12-25, 30-34, 38-44, 50-65 73-74 and 105-107 - Miura, Wang, Northrup. and Turner

Claims 1-4, 12-25, 30-34, 38-44, 50-65 73-74 and 105-107 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,132,012 to Miura et al. (hereinafter “Miura”) in view of U.S. Patent 5,663,488 to Wang et al. (hereinafter “Wang”), and further in view of U.S. Patent 5,882,496 to Northrup et al. (hereinafter “Northrop”) and U.S. Patent 5,885,869 to Turner et al. (hereinafter “Turner”). Applicant submits that the combination of these references does not teach or suggest the presently claimed invention.

It is respectfully submitted that the Office has not established a *prima facie* case of obviousness. The case of Ex parte Obukowicz, 27 U.S.P.Q.2d 1063 (B.O.P.A.I. 1993) sets forth the current case law regarding Section 103 rejections:

In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. In re Piasecki, 745 F.2d 1468, 1471-72, 223 U.S.P.Q. 785, 787-88

¹ The Examiner, at page 6 of the Official Action, states that claim 42 is indefinite. The text of Claim 42 does not apply to the Examiner’s statements. Applicants assume that reference to Claim 42 was incorrect, and that the Examiner meant to write “46”. Applicants have addressed the problem as such.

(Fed. Cir. 1984). The examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art *would lead* that individual to combine the relevant teachings of the references. In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Indeed, the teachings of references can be combined only if there is some suggestion or incentive to do so. ACS Hospital Systems, Inc. v. Montefiore Hospital, 723 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

The Applicant submits that the instant invention is not taught or suggested in the prior art. The Federal Circuit has stated that a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered. Bausch & Lomb, Inc. v. BarnesHind/Hydrocurve, Inc., 230 U.S.P.Q. 416 (Fed. Cir. 1986). The prior art references cited by the Examiner “would likely *discourage* the art worker from attempting the substitution suggested by [the applicant].” Gillette Co. v. S.C. Johnson & Son, Inc., 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990). Additionally, “it is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teaching of the prior art so that the claimed invention is rendered obvious One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

The references cited by the Examiner do not teach or suggest a matrix with a first porous region extending a distance across a semiconductor substrate.

The Examiner, at pages 7-8, states that Miura teaches all of the limitations of the present invention except for the integration of a migration facilitator, the integration of a thermal detector, the incorporation of porous silicon and/or hemispherical grain silicon into separation columns. The Examiner also admits that Miura fails to teach an electrophoretic device. Furthermore, the Examiner notes that Miura fails to teach incorporation of a reaction region in order to form a capture system, or teach the use of internal references or controls. However, the Examiner also asserts that it would be obvious to create a separation apparatus of the present invention because Miura discloses a separation column and indicates the difficulty in miniaturization of a liquid column chromatograph.

The Applicant respectfully disagrees with the Examiner's assessment of Miura. Miura discloses a liquid chromatograph with a detector for analyzing component ions. The liquid chromatograph contains a planar plate which is bonded to the surface where the flow path is defined by the planar surface. Miura further provides a field effect transistor type chemical sensor. Furthermore, Miura teaches that the capillary column of the chromatograph comprises an open channel, or conduit.

Wang teaches a gas chromatograph that contains a pumping assembly. Notably, Wang does not teach a matrix comprising of a first porous region. Therefore, the lack of contemplation of teaching a matrix makes the attempted combination of Wang with Miura a case of unreasonable hindsight. In particular, there is no motivation to combine these two references since Wang and Miura, either alone or in combination, fail to teach or suggest the use of a sample separation apparatus comprising of a semiconductor substrate and a matrix comprising of a porous region.

Northrop, which is cited for supplying disclosure of porous silicon that can be used in a separation channel, does not actually disclose the use of a porous silicon or other matrix in a separation channel. Moreover, Northrop lacks any disclosure of the use of porous silicon or another matrix material to separate the constituents of a sample. Rather, at column 6, lines 20-37, Northrop teaches a smooth, open electrophoresis channel 44 formed by grooves or microchannels. The porous silicon disclosed by Northrop does not form the channels, but only serves as a valve between a PCR apparatus and an electrophoresis apparatus.

The Examiner also cites to Turner as teaching the use of hemispherical grain silicon. Turner teaches a method of fabricating semiconductors relating to the uniform doping of hemispherical grain polycrystalline silicon. Turner does not even contemplate separating the constituents of a sample in a chromatograph, electrophoretic apparatus, or other separation device. The Federal Circuit has stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). Therefore, the lack of contemplation by Turner

toward the present invention makes the combination of Miura, Wang, Northrop, and Turner a case of unreasonable hindsight construction.

The present application includes claims for a separation apparatus that comprises of a semiconductor substrate as well as a porous region that includes a matrix. The surface area of the matrix of each capillary column facilitates the separation of the constituents of a sample over a relatively short length of the column compared to the required lengths of conventional smooth, "open", etched or ablated columns to effectively separate the constituents. As noted in the as-filed application, it is the use of these substantially smooth, open-channeled capillary columns in miniature chromatographs that imposes size limitations the present invention teaches away from. The open-channel capillaries are undesirable from the standpoint that open-channeled columns typically have a surface area that is limited by the area of the substantially smooth surface of the channel. The amount of stationary phase material that may be disposed along a given length of substantially smooth, open-channeled capillary columns is limited by the surface area of that length of the capillary column. Thus, in order to effectively separate the various constituents of a sample, the capillary column must be relatively long. Consequently, the substrate on which the capillary column is formed must have a sufficient surface area to facilitate fabricating the capillary column thereon. Thus, the use of the open-channeled capillaries recited by Miura would actually discourage a person of knowledge in the art from utilizing a porous region including a matrix to facilitate the separation of the constituents.

None of Miura, Wang, Northrop or Turner, either alone or in combination, teaches or suggests all the claim limitations of claims 1, 30, 51, 57, 64 and 105 of which claims 2-4, 12-25, 29, 31-34, 38-44, 50, 52-56, 58-63, 65, 73-74 and 106-107 subsequently depend upon. Particularly, each of these references lacks any teaching or suggestion of a channel comprising a porous matrix.

It is respectfully submitted that the sample separation apparatus recited in claim 1, as amended, of the present application is not at all identical to the structures cited in Miura, Wang, Northrop and Turner. Claim 1 recites a sample separation apparatus with "a matrix comprising a first porous region extending a distance across said semiconductor substrate". None of Miura,

Wang, Northrop, or Turner, however, teaches or suggests a matrix or a porous region that extends a distance across a semiconductor substrate. Therefore, claim 1 as amended is allowable over the aforementioned patents.

Claim 2 has been canceled without prejudice or disclaimer.

Claims 3-4 and 12-25 are each allowable as depending from claim 1.

Independent claim 30, as amended, is allowable for substantially the same reasons mentioned above with respect to claim 1. Specifically, none of Miura, Wang, Northrop or Turner teaches or suggests a separation apparatus with “at least one capillary column formed in [a] substrate and comprising a . . . porous matrix.”

Claims 31-34 and 38-44 are each allowable as depending from claim 30.

Independent claim 51 is allowable in that it recites a miniature chromatograph comprising a substrate and “a porous matrix formed in said substrate and comprising at least one capillary column, said porous matrix comprising a plurality of pores.” Again, none of Miura, Wang, Northrop, or Turner teaches or suggests a porous matrix with a plurality of pores that comprises a capillary column.

Claims 52-56 are each allowable as depending from claim 51.

Independent claim 57 is allowable for the same reasons provided above with respect to claim 30 and additionally because it recites an electrophoretic apparatus including a semiconductor substrate and “at least one sample column in said semiconductor substrate and comprising a first end, a second end, and a first porous matrix which comprises a first plurality of pores.” None of Miura, Wang, Northrop, or Turner teaches or suggests an electrophoretic apparatus with at least one sample column having a porous matrix with a plurality of pores. Therefore, none of Miura, Wang, Northrop, or Turner, taken alone or in combination, renders obvious the subject matter recited in claim 57 as amended.

Claims 58-63 are each allowable as depending from claim 57.

Claim 58, as amended, is further allowable as it recites first and second electrodes that are both situated proximate to the respective first and second ends of a sample column. None of

Miura, Wang, Northrop, or Turner teaches or suggests an electrophoretic apparatus with electrodes so positioned.

Independent claim 64 is allowable as it recites a semiconductor substrate and a porous column formed in said semiconductor substrate. None of Miura, Wang, Northrop, or Turner teaches or suggests a separation apparatus with a porous column.

Claims 65 and 73-74 are each allowable as depending from claim 64.

Independent claim 105 is allowable as it recites a flow channel device with a “flow channel comprising a matrix formed of hemispherical grain silicon”. None of Miura, Wang, Northrop, or Turner teaches or suggests a flow channel comprising a matrix formed of hemispherical grain silicon. Thus, none of Miura, Wang, Northrop, or Turner, taken alone or in combination, renders obvious the subject matter recited in claim 105 as amended.

Claims 106 and 107 are each allowable as depending from claim 105.

Moreover, it is respectfully submitted that one of ordinary skill in the art would not be motivated to combine the references in the manner that has been suggested in the outstanding Office Action. While Northrop teaches the use of porous silicon as a controllable valve, none of Miura, Wang, Northrop, or Turner suggests that porous silicon would be useful in a separation column or other apparatus that separates the constituents of a sample from one another.

Similarly, although Turner teaches hemispherical grain silicon, none of the cited references would have motivated one of skill in the art to use the hemispherical grain silicon taught in Turner in a sample separation column.

Further, as the cited references would not have provided one of skill in the art with motivation to use porous silicon or hemispherical grain silicon in a sample separation apparatus, it is respectfully submitted that the combination set forth in the outstanding Office Action constitutes impermissible hindsight reconstruction of the invention recited in the claims of the referenced application.

In view of the foregoing arguments, reconsideration and withdrawal of the Section 103 rejection to claims 1, 3-4, 12-25, 29, 30-34, 38-44, 50-65, 73-74, and 105-107 is respectfully requested.

Claims 1-12, 14-17, 25-38, 42-52, 54-69, 71-74 and 105-107 - Miura, Swedberg, Sunzeri, Northrop and Turner

Claims 1 through 12, 14 through 17, 25 through 38, 42 through 52, 54 through 69, 71 through 74, and 105 through 107 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Miura in view of U.S. Patent 5,571,410 to Swedberg et al. (hereinafter "Swedberg") and U.S. Patent 5,536,382 to Sunzeri (hereinafter "Sunzeri"), and further in view of Northrop and Turner. The Applicant submits that the combination of these references does not teach or suggest the presently claimed invention.

As previously discussed, a *prima facie* case of obviousness cannot be established where, as in the instant case, the teachings of the references teach away from the invention as presently claimed in the application, or where no suggestion or incentive to combine the references can be shown. Specifically, a suggestion to combine cannot be shown where the references are drawn to entirely different inventions or problems.

Swedberg, like the references discussed above, teaches that the capillary column of the chromatograph comprises an open channel, or conduit, with a substantially smooth surface. This is precisely contrary to what the present invention teaches. The present invention teaches a sample separation apparatus comprising a semiconductor substrate as well as a matrix comprising of a first porous region. Thus, a person in the art would be discouraged by Swedberg from developing the present invention.

The Applicant respectfully disagrees with the Examiner's assessment of Sunzeri. Sunzeri teaches a method for analyzing constituents using capillary electrophoresis. Sunzeri does not teach or suggest the present invention of a sample separation apparatus comprising a semiconductor substrate and a matrix comprising of a porous region. Therefore, the lack of contemplation by Sunzeri towards the present invention would result a a case of unreasonable hindsight.

The Applicant also respectfully disagrees with the Examiner's remarks regarding Miura, Northrop and Turner. As noted in the prior sections of this Amendment, Miura, Northrop and Turner each fail to disclose the matrix of the present application. The prior art is limited to a

large surface area that fails to contain a matrix. Thus, none of Miura, Swedberg, Sunzeri, Northrop or Turner, either alone or in combination, teaches or suggests all the limitations of claims 1, 30, 51, 57, 64 and 105 of which claims 3-12, 14-17, 25-29, 31-38, 42-50, 52, 54-56, 58-63, 65-69, 71-74 and 106-107 subsequently depend upon.

In particular, none of Miura, Swedberg, Sunzeri, Northrop, or Turner teaches or suggests a sample separation apparatus including a silicon substrate and "a matrix comprising a first porous silicon region extending a distance across said semiconductor substrate." Accordingly, it is respectfully submitted that the sample separation apparatus recited in claim 1, as amended, of the present application is not at all identical to the structures cited in Miura, Swedberg, Sunzeri, Northrop and Turner. Therefore, claim 1 as amended is allowable over the aforementioned patents.

Claim 2 has been canceled without prejudice or disclaimer.

Claims 3-12, 14-17, and 25-29 are each allowable as depending from claim 1.

Independent claim 30, as amended, is allowable for substantially the same reasons as mentioned with respect to claim 1. Specifically, none of Miura, Swedberg, Sunzeri, Northrop, or Turner teaches or suggests a separation apparatus having "at least one capillary column . . . comprising a . . . porous matrix".

Claims 31-38 and 42-50 are each allowable as depending from claim 30.

Independent claim 51 as amended is also allowable in that it recites a miniature chromatograph with a substrate and "a porous matrix formed in said substrate and comprising at least one capillary column, said porous matrix comprising a plurality of pores." None of Miura, Swedberg, Sunzeri, Northrop, or Turner teaches or suggests a miniature chromatograph with such a porous matrix. Thus, Miura, Swedberg, Sunzeri, Northrop, and Turner, taken alone or in combination, do not render obvious claim 51 as amended.

Claims 52, 54-56 are each allowable as depending from claim 51.

Independent claim 57 is allowable for the same reasons stated above with respect to claim 30, and additionally because claim 57 recites an electrophoretic apparatus with a semiconductor substrate and "at least one sample column in said semiconductor substrate and

comprising a first end, a second end, and a first porous matrix which comprises a first plurality of pores". Claim 57 also recites a control column with a second porous silicon matrix that is similar to the first porous silicon matrix of the sample column. None of Miura, Swedberg, Sunzeri, Northrop, or Turner teaches or suggests an electrophoretic apparatus with such a sample column and control column. Accordingly, Miura, Swedberg, Sunzeri, Northrop, and Turner, taken alone or in combination, do not render claim 57 as amended obvious.

Claims 58-63 are each allowable as depending from claim 57.

Claim 58, as amended, is further allowable as it recites first and second electrodes that are both situated proximate to the respective first and second ends of the sample column. None of Miura, Swedberg, Sunzeri, Northrop, or Turner teaches or suggests electrodes so positioned.

Independent claim 64 is allowable as it recites a semiconductor substrate and a porous column formed in a semiconductor substrate that is not taught or suggested by any of Miura, Swedberg, Sunzeri, Northrop, or Turner.

Claims 65-69 and 71-74 are each allowable as depending from claim 64.

Independent claim 105 is allowable as it recites a flow channel device with a "flow channel comprising a matrix formed of hemispherical grain silicon." None of Miura, Swedberg, Sunzeri, Northrop, or Turner teaches or suggests a flow channel with a matrix formed of hemispherical grain silicon.

Claims 106 and 107 are each further allowable as depending from claim 105.

Moreover, it is respectfully submitted that one of ordinary skill in the art would not be motivated to combine the references in the manner that has been suggested in the outstanding Office Action. While Northrop teaches the use of porous silicon as a controllable valve, none of Miura, Swedberg, Sunzeri, Northrop, or Turner suggests that porous silicon would be useful in a separation column or other apparatus that separates the constituents of a sample from one another.

Similarly, although Turner teaches hemispherical grain silicon, none of the cited references would have motivated one of skill in the art to use the hemispherical grain silicon taught in Turner in a sample separation column.

Further, as the cited references would not have provided one of skill in the art with motivation to use porous silicon or hemispherical grain silicon in a sample separation apparatus, it is respectfully submitted that the combination set forth in the outstanding Office Action constitutes impermissible hindsight reconstruction of the invention recited in the claims of the referenced application.

In view of the foregoing arguments, reconsideration and withdrawal of the Section 103 rejection to claims 1, 3-12, 14-17, 25-38, 42-52, 54-69, 71-74, and 105-107 is respectfully requested.

CONCLUSION

In view of the foregoing amendments, and further in view of the arguments made, it is believed that this application is now in condition for allowance. Reconsideration and early Notice of Allowance is respectfully requested. If any issues preventing the allowance of the application remain that may be resolved by way of a telephone conference, the Office is respectfully invited to contact the undersigned at the telephone number indicated below.

Respectfully Submitted,



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